EUROPEAN COMMISSION

Brussels, 24.1.2011
C(2011)471

COMMISSION DECISION

of 24.1.2011

amending the marketing authorisation granted by Decision C(2004)3653 for "Apidra - Insulin glulisine", a medicinal product for human use

(ONLY THE GERMAN TEXT IS AUTHENTIC)

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[1],

Having regard to Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products[2], and in particular Article 17(2) thereof,

Having regard to the application submitted on 22 August 2010 by Sanofi-Aventis Deutschland GmbH under Article 16 of Regulation (EC) No 1234/2008,

Having regard to the notification submitted by Sanofi-Aventis Deutschland GmbH, under Article 15(1) of Regulation (EC) No 1234/2008,

Having regard to the opinion of the European Medicines Agency, formulated on 16 December 2010 by the Committee for Medicinal Products for Human Use,

Whereas:

(1) The European Medicines Agency has informed the marketing authorisation holder and the Commission of its favourable opinion on the major variation type II and of the need to amend the marketing authorisation for the medicinal product "Apidra - Insulin glulisine" which is entered in the Community Register of Medicinal Products under numbers EU/1/04/285/001-036.

(2) The European Medicines Agency has informed the marketing authorisation holder and the Commission of its favourable opinion on a minor variation notified between 13 October 2010 and 16 December 2010.

(3) The marketing authorisation should be updated and Decision C(2004)3653 of 27 September 2004 should therefore be amended accordingly. The Community Register of Medicinal Products should also be updated.

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1 OJ L 136, 30.4.2004, p. 1.
2 OJ L 334, 12.12.2008, p. 7.

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2004)3653 is amended as follows:

1) The following notification for a minor variation is added to the marketing authorisation:

Application number	Scope (EU numbers affected)
EMEA/H/C/557/IB/31	B.IV.1.a).1 (EU/1/04/285/005-012)

2) Annex I is replaced by the text set out in Annex I to this Decision;

3) Annex II is replaced by the text set out in Annex II to this Decision;

4) Annex III is replaced by the text set out in Annex III to this Decision.

Article 2

This Decision is addressed to Sanofi-Aventis Deutschland GmbH, D-65926 Frankfurt am Main, Deutschland.

Done at Brussels, on 24.1.2011.

For the Commission
Paola TESTORI COGGI
Director-General